

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application No. 10/580,753

Applicant: Duggan, et al.

Filed: May 26, 2006

TC/AU: Not yet assigned

Examiner: Not yet assigned

Docket No.: 252805

Customer No.: 23460

Title: COMPOSITION AND DELIVERY SYSTEM

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under

37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
    - the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
    - or*
    - the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
  - after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
  - after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### **Copies of the References**

- Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.
- Copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.
- Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- A copy of the foreign search report is enclosed herewith.

- The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

| U.S. APPLICATIONS |                  | STATUS (check one) |         |           |
|-------------------|------------------|--------------------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED           | PENDING | ABANDONED |
| 1.                |                  |                    |         |           |
| 2.                |                  |                    |         |           |
| 3.                |                  |                    |         |           |

**Statement under 37 CFR 1.97(e)**

- The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- No fee** is owed by the applicant(s).
- Charge Deposit Account No. 12-1216 in the amount of **\$180.00** (37 CFR 1.17(p)).  
(A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

- Credit Account No. 12-1216.  
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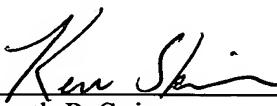
  
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Date: July 14, 2006

**CERTIFICATE OF MAILING**

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date shown below and is addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 14, 2006

  
Kenneth P. Spina

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|--|---|----|---|--------------------------|------------------|
| Substitute for form 1449A/B/PTO  |   |    |   | <i>Complete if Known</i> |                  |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |   |    |   | Application Number       | 10/580,753       |
|  |   |    |   | Filing Date              | May 26, 2006     |
|  |   |    |   | First Named Inventor     | DUGGAN, Alex     |
|  |   |    |   | Group Art Unit           | Not yet assigned |
|  |   |    |   | Examiner Name            | Not yet assigned |
| Sheet  | 1 | of | 1 | Attorney Docket Number   | 252805           |

| OTHER - NON PATENT LITERATURE DOCUMENTS |          |   |             |                  |
|---|----------|---|-------------|------------------|
| Examiner Initials                       | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.    | Translation |                  |
|   |          |   | Yes         | No <sup>**</sup> |
|   | AC       | International Search Report for International Application No. PCT/GB2004/005010, September 14, 2005, 4 pages.   |             |                  |
|   | AD       | Written Opinion of the International Searching Authority for International Application No. PCT/GB2004/005010, 8 pages.  |             |                  |
|   | AE       | International Preliminary Report on Patentability for International Patent Application No. PCT/GB2004/005010, May 29, 2006, 10 pages.   |             |                  |
|   | AF       | GAUBERT, et al., Antigen Delivery Using Spherulites™ Induces Strong Antibody Responses by Different Routes of Immunization, <i>Proceed. Int'l Symp. Control. Rel. Bioact. Mater.</i> , 27(2000) <i>Controlled Release Society, Inc.</i> , July 2000, pages 570-571. |             |                  |
|   | AG       | FREUND, Biodistribution and Gastrointestinal Drug Delivery of New Lipidic Multilamellar Vesicles, <i>Drug Delivery</i> , vol. 8, pages 239-244, 2001.   |             |                  |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

- + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).